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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,555	11/15/2001	Gregory Paul Dittmar	8341	2834

27752 7590 08/25/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

**Application No.**

09/996,555

**Applicant(s)**

DITTMAR ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 14-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-7-04.
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of notice of appeal filed 03/18/04; IDS, amendment, remarks and request for continued examination filed 06/17/04. Claims 1-11 and 14-35 are pending.

### **NEW MATTER**

The recitation of applied "directly" introduces new matter into the claims that is not supported by the specification as originally filed.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 and 14-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 11 recite applying an outer coating layer directly on the inner coating layer. This action is not supported by the specification as originally filed. A disclosure in the specification on page 13, line 7, stating that an outer "coating is applied immediately following the application of the inner coating or once the inner coating has cured" does not constitute support for a direct action.

*Claim Rejections - 35 USC § 102*

3. Claims 1-4, 8-11, 14, 19-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Iamartino et al. (US 5,171,580, cited by applicants on form PTO 1449).

Iamartino discloses an oral pharmaceutical preparation that comprises a core of active ingredient coated with three protective layers (abstract, column 3, lines 15-20). Iamartino states that coating the core of therapeutically active agents with the three layers allows specific and reliable release of the active substance directed to the lower part of the intestine and especially to the large intestine or colon (column 3, lines 8-13). The cores are prepared either by granulation or tableting and the tablets or cores that are coated are included in hard gelatin capsule dosage units (column 5, lines 9, 10, 27-35 and claim 1). Iamartino manufactures tablets using a tablet press (column 5, lines 57-59) and pressing in a tablet press produces compressed tablets. Regarding claim 22, although, Iamartino includes about 10 coated tablets or cores in a capsule (column 5, lines 27-55), Iamartino nonetheless teaches the manufacture of tablet-by-tablet press and thus Iamartino's coated pressed tablet meets the scope of claim 22.

The active agents of Iamartino are 5-aminosalicylic acid (5-ASA) or corticoids for treating colonic and rectal disorders, antibacterial agents and antibiotics for treating local infectious diseases of the large intestine, anti-tumor chemotherapeutic agents for cancer therapy of the large intestine, cimetropium bromide antispasmodic drug, ketoprofen and ibuprofen non steroidal anti-inflammatory agents, and peptide or protein drugs (column 4, line 35 to column 5 line 2). Iamartino exemplifies the pharmaceutical preparation with ketoprofen (example 1), cimetropium bromide (example 2) and toluidine blue (example 3).

Art Unit: 1615

An inner coating layer in Iamartino comprises plasticizer and anionic copolymer EUDRAGIT S where the ratio of free carboxyl group to the ester group is 1:2 and the amount of the copolymer is in the range of 10-30% by weight gain on the core and it is suggested that a film thickness of 40-120 microns would ensure a quick dissolution of the coating layer at above pH 7.0 (column 3, lines 21-23 and lines 36-57).

An intermediate layer of gelling polymer (column 3, lines 24-26) comprises cellulose derivatives (column 3, lines 58-68). An outer layer of gastro-resistant polymer (column 3, lines 28-30) comprises common enteric material that are selected from cellulose acetate phthalate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate, hydroxyethyl cellulose phthalate, cellulose acetate tetrahydrophthalate and EUDRAGIT L that dissolves at pH 5.5 (column 4, lines 21-29). The thickness of the outer layer in example 1 of Iamartino is listed as about 30 microns and the purpose of the outer layer is to enable the preparation to quickly dissolve in the intestine (column 3, lines 28-30).

The EUDRAGIT S of Iamartino is the poly(methacrylic acid, methyl methacrylate) 1:2 copolymer recited in instant claims 1-4 and 11-15. EUDRAGIT L is the poly(methacrylic acid, methyl methacrylate) 1:1 copolymer recited in instant claims 1-4 and 11-15. EUDRAGIT L, which is used in the outer layer differs from EUDRAGIT S of the inner layer. Instant claims 1 and 11 are a pharmaceutical composition that comprises a, b and c and the comprising language does not exclude the presence of the intermediate layer in Iamartino.

The teaching of Iamartino meets the limitations of the claims.

Applicants argue that the prior art, Iamartino's dosage form has an extra layer that the instant dosage form does not. However, there is no demonstration as to what the absence of an intermediate layer does for the instant tablet dosage form.

Art Unit: 1615

4. The rejection of claims 1-4, 8, 9, 11, 14, 19, 20 and 22 under 35 U.S.C. 102(b) as being anticipated by Rommelmayer (WO 98/27967, provided by applicants on form PTO 1449) is withdrawn because the outer coating of Rommelmayer differs from the outer coating required by instant claims 1 and 11. Applicants' argument with respect to Rommelmayer is persuasive.

***Claim Rejections - 35 USC § 103***

5. The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Rommelmayer (WO 98/27967, provided by applicants on form PTO 1449) is withdrawn because Rommelmayer does not disclose the conditions of part c of claims 1 and 11.

6. Claims 57, 16-18 and 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iamartino et al. (US 5,171,580, cited by applicants on form PTO 1449).

Iamartino clearly teaches the oral formulation of the instant invention by teaching tablets or cores of active agents that are coated by an inner layer comprising EUDRAGIT S (poly(methacrylic acid, methyl methacrylate) 1:2), an intermediate gelling polymer layer and outer layer comprising EUDRAGIT L (poly(methacrylic acid, methyl methacrylate) 1:1) and the tablets are included in a capsule such that the overall dosage form is a capsule (claim 1 and example 1).

Regarding instant claims 7 and 18 that recite the process of making the coated solid dosage form, although Iamartino teaches continuous spray coating of the tablets or cores with the coating layers, it is respectfully submitted that Iamartino teaches coated active cores or tablets and how the coated core is prepared is not critical in a formulation claim. Regarding the amounts of active agent recited in claims 26, 27, 31 and 32, the amounts of the drug does not accord patentability of the instant claims over Iamartino with out a showing that the recited amount is critical to the dosage form.

However, while Iamartino teaches inner layer coating and outer layer coating that has a thickness of from about 40 micron (inner layer) plus 30 micron (outer layer) to about 120 micron (inner layer) plus 30 micron (outer layer), that is, from about 70 micron to about 150 micron, Iamartino does not give the thickness of the coating layers in  $\text{mg}/\text{cm}^2$ . It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply to the cores or tablets an inner and outer coating layer of certain thickness since Iamartino teaches that the thickness of the coating layers determines the quick dissolution of the coating layer (column 3, lines 48 and 49). One having ordinary skill in the art would have been motivated to optimize the thickness of the coating layer determined either in microns or  $\text{mg}/\text{cm}^2$  with the expectation of producing desired quick dissolution of the coating layer.

7. The rejection claims 23 and 24 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rommelmayer (WO 98/27967, provided by applicants on form PTO 1449) is withdrawn and applicants' argument is persuasive.

8. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iamartino et al. (US 5,171,580, cited by applicants on form PTO 1449).

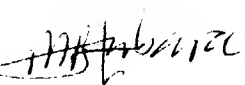
Iamartino discloses the orally administrable formulation of claims 1 and 11 where the coating layer determines the release of active agents in the intestines. Thus the teaching of Iamartino encompasses the scope of claims 23 and 24. In the alternate, the method of administering the formulation of claims 1 and 11 to the gastrointestinal tract is explicit in Iamartino because the formulation of Iamartino, which anticipates claims 1 and 11 is orally administrable and therefore one would be motivated to orally administer the formulation of Iamartino to the gastrointestinal tract.

Applicants' argument that Iamartino teaches a three-layer composition while the instant claims teach a two-layer composition is not persuasive because the instant claims comprises and this comprising does not exclude an intermediate layer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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